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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,688	10/28/2003	Jeroen Mattijs Bezemer	05032-00044	3925

22910 7590 05/25/2005

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EXAMINER

BERKO, RETFORD O

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 05/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/694,688

Applicant(s)

BEZEMER ET AL.

Examiner

Retford Berko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

**Acknowledgement:** The Amendment filed 2/8/05 is acknowledged

### **Status of Claims**

Applicant cancelled claim 7; claims 1-6 and 8-16 are in the application.

Withdrawal of Claim Rejections-35 USC Sec 112:

1. The rejection of claims 1-2 and 5-11 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of applicant's amendment to the claims.
2. The rejection of claims 1-14 remain rejected under 35 U.S.C. under 35 U.S.C. 103(a) as being unpatentable over McGinity et al (US 5, 288, 502) in view of Subramaniam et al (US 5, 874, 029) further in view of Goedemoed et al (US 5, 980, 948) is withdrawn in view of applicant's remarks that the Preliminary Amendment filed on 10/28/03 was not considered during examination and issuance of the first non-final office action of 9/9/04.

**New Grounds of Rejection:**

### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6 and 7 of U.S. Patent No. 6, 685, 957. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the instant application, like the claims in Patent '957 are drawn toward a process for preparing implant for controlled release and delivery of bioactive agent (peptide, oligopeptide and protein); both processes comprising a wet spinning technique (col 14, see claims 1, 6 and 7).

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 8-16 are rejected under 35 U.S.C. under 35 U.S.C. 103(a) as being unpatentable over Vancaty et al (US 6, 348, 069; filed 11/3/1998) in view of Martin et al (US 6, 162, 537; filed 10/31/1997).

Vacanti et al (Patent '069) discloses a method for making polymer cell-matrix constructs for implantation into the body (abstract, col 3, lin 11-20 and col 12, lin 1-5). Vancaty discloses

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polymer fibers as implants as scaffold for tissue engineering (col 7, lin 22, lin 54 and col 8, lin 21). Vancati discloses incorporation of bioactive molecules into the polymer matrix for delivery or release into sites (col 6, lin 14-24; e.g. cyclosporine, see col 6, lin 48).

Vancati et al do not disclose the specific details of making the polymer fibers and does not disclose wet spinning technique.

Martin et al (Patent '537) discloses wet spinning technique as process for making implantable bio-component fibers (col 4, lin 1-5, lin 29-35 and col 10, lin 40-45 and claim 15 at col 18, lin 1-15). Martin discloses that the polymer fibers (col 9, lin 12-22) may be combined with active agents during fabrication into medical devices (col 8, lin 15-20 and lin 55-58).

One of ordinary skill would be motivated to prepare polymer fibers using wet spinning technique and incorporate therein active agents for implantation into specific tissue sites (Martin et al (col 4, lin 1-10 and lin 30-35). One of ordinary skill would expect to the beneficial effect of the drug when released into the sites (Martin, col 8, lin 15 and Vancati, col 6, lin 14-24). Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill at the time it was made.

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 703-305-4442. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



NEIL S. LEVY  
PRIMARY EXAMINER